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02/18/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/559,996

Applicant(s)

KRAHMER ET AL.

Examiner

RONALD T. NIEBAUER

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 4-12 and 15-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 13-14, 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants arguments filed 12/7/09 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

As stated previously, applicants elected Group I and the species, where Z is formula Xc (see specification page 15) in which b is 2, c is 2, d is 3, P is H and R1 is C5 alkoxy residue; W is hydrogen; X is CH₃-(O-CH₂CH₂)₃-OH wherein X is attached through the OH group; V is tetraethylene glycol. The species has been interpreted as being of formula Ia since there is no X in formula Ib. Since the valency of oxygen would not be proper (oxygen would be bonded to a carbon, hydrogen, and nitrogen) as stated by applicant, the X has been taken to be attached via the O (not an OH) such that the oxygen is bonded to a nitrogen and carbon. The elected species was found to be free of the prior art. In accord with section 803.02 of the MPEP the search was then extended to other species and art was found that reads on species of the instant claims. As such, the examination has been extended to the extent necessary to determine patentability of the Markush-type claim. Further section 803.02 of the MPEP states that the prior art search, however, will not be extended unnecessarily to cover all nonelected species. In order to advance prosecution, claim 21 has been included in the instant examination since art cited herein reads on claim 21. Claim 3 has been included in the instant examination since art cited herein reads on claim 3.

In the instant case, claims 6-8,16 are in different groups than the elected group. In the instant case, claims 4-5,9-12,15,17-20 include other features than the originally elected species and the cited art does not read on the claims.

Claims 6-8,16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/15/08.

Claims 4-5,9-12,15,17-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/15/08.

Claims 1-3,13-14,21 are under consideration.

Claim Rejections - 35 USC § 102

Claims were previously rejected under 102 based on the Rathore reference. The rejection is maintained.

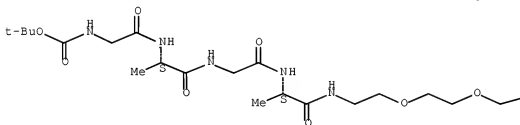
Claims were previously rejected under 102 based on the Biessen reference. The rejection is maintained.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

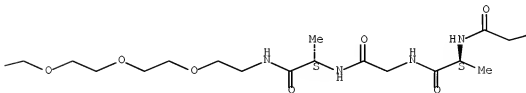
A person shall be entitled to a patent unless –

Claims 1-3,13-14,21 are rejected under 35 U.S.C. 102(b) as being anticipated by Rathore et al. (Journal of Polymer Science , Part A:Polymer Chemistry, 2000 v38(2) pages 352-366; first cited on 6/25/08).

Rathore teach copolymers containing polyethylene glycol segments and peptide segments (abstract). In scheme 1 (page 357) Rathore teach structure 6 (Boc-GAGA-HN(CH₂CH₂O)5-CH₂CH₂NH-AGAG-Boc). It is noted that the structures of the amino acids of structure 6 are shown in chart 1 (page 353) and scheme 2 for example. Structure 6 of Rathore is:

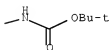


PAGE 1-A



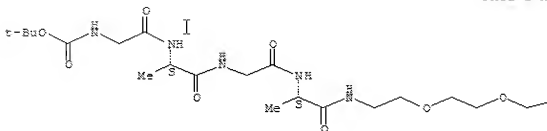
PAGE 1-B

PAGE 1-C



Below is a marked up structure relating the structure of Rathore to the instant claims.

PAGE 1-A

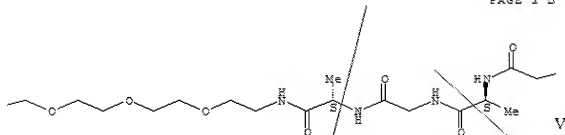


Z

R1'

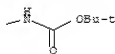
R1''

PAGE 1-B



N(H)C(O)C(W2)N(X)C(O)

PAGE 1-C



In comparison to the instant invention the compound of Rathore is of formula Ia of claims 1,21 of the instant invention. Specifically, Z (see the above structure label 'Z') is Boc-Gly-Ala-Gly-Ala-NH-(CH₂CH₂O)₅-CH₂CH₂NH-C(O)C(CH₃). Thus Z is a hydrocarbon residue which contains heteroatoms as recited in the instant claims. Further the compound of

Rathore includes $N(H)C(O)C(W_2)N(X)C(O)$ (see above) as in formula Ia of the instant invention. Each occurrence of W is hydrogen. Each occurrence of X is hydrogen. V is $C(CH_3)NHC(O)-CH_2-NH-C(O)-Boc$. Thus V is a hydrocarbon residue which contains heteroatoms as recited in the instant claims. Further, the claims recite that the residues V, W, X, and Z together comprise at least two residues which have formula IIa. In the instant case, Z comprises at least two residues which have formula IIa: $CH_2-O-CH_2CH_2-O-(CH_2-CH_2-O)_3-CH_2-CH_2$ (which is labeled as R1' above) where R1 is a hydrocarbon with 1 to 10 carbon atoms with heteroatoms as recited in the instant claims; $CH_2-O-(CH_2-CH_2-O)_3-CH_2-CH_2$ (which is labeled as R1'' above) where R1 is a hydrocarbon with 1 to 10 carbon atoms with heteroatoms as recited in the instant claims.

It is noted that claim 3 recites that the compound comprises at least 3 residues which have formula IIa. In addition to R1' and R1'', the compound of Rathore also comprises $CH_2CH_2-O-(CH_2-CH_2-O)_3-CH_2-CH_2$ thus meeting the limitation of claim 3.

It is noted that claim 2 recites that Y (which can be a part of any of V, W, X, and Z) is able to bind a wide range of groups. Although the office has no facility to test the binding capabilities of the compound of Rathore, due to the variety of groups contained in the compound of Rathore there is a reasonable basis that the compound meets the limitations of claim 2, absence evidence to the contrary. Scheme 2 (page 357) shows that the NH residues, for example, can act in hydrogen bonding and as such the compound contains a binding group Y thus meeting the limitations on Y recited in claims 1,21 of the instant invention. The compound of Rathore meets the structural limitations of claims 1,21 of the instant invention.

Rathore teach (page 355 1st column last two paragraphs) the synthesis of structure 6 in solution so the compound is necessarily part of a composition thus meeting the structural limitations of claims 13-14 of the instant invention. It is noted that the recitation of 'diagnostic' in claim 14 does not result in a structural difference. As such Rathore meet the limitations of claims 1-3,13-14,21 of the instant invention.

Response to Arguments 102 rejection Rathore

Applicants argue (pages 9-11) that the same residue is counted in order to meet the claim limitations.

Applicants argue that a nine carbon chain does not read on 'comprise a three carbon residue'.

Applicants argue that the residues are terminal residues.

Applicants argue that Boc-GAGA has 15 carbons and cannot meet the claim limitations.

Applicant's arguments filed 12/7/09 have been fully considered but they are not persuasive.

Although Applicants argue (pages 9-11) that the same residue is counted in order to meet the claim limitations, it is noted that the claim expressly recites 'together comprise at least two residues which have'. A residue is a portion of a molecule. For example, the tripeptide Ala-Pro-Gly contains 2 dipeptide residues – Ala-Pro and Pro-Gly. Whether or not Pro is a component of both dipeptides does not negate that fact that there are 2 dipeptide residues. In the instant claims, the compound of Rathore contains the residues as claimed. Further, it is noted that the claims expressly recite 'have formula'. In accord with section 2111.03 of the MPEP the transitional phrase 'have' is interpreted as open- ended language.

Although Applicants argue that a nine carbon chain does not read on 'comprise a three carbon residue', section 2111.03 of the MPEP recites:

"The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term comprising,' the terms containing' and mixture' are open-ended."); < Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts)"). Thus, a nine carbon chain does read on 'comprise a three carbon residue'. In the instant case, the claim recites 'comprise at least' and 'have formula'. As such, the claims are clearly open to additional elements. Further, the claims use the phrase 'residue' which is a portion of a larger molecule. Thus, it is reasonable to interpret the residue as a portion of a larger molecule.

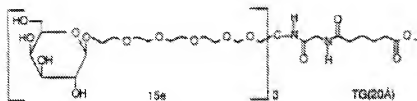
Although Applicants argue that the residues are terminal residues, such limitation does not appear in the claims. In the instant case, the claim recites 'comprise at least' and 'have formula'. The claim recites that R1 'has'. As such in accord with section 2111.03 of the MPEP, the claims are clearly open to additional elements.

Although Applicants argue that Boc-GAGA has 15 carbons and cannot meet the claim limitations, it is noted that R1 is part of a formula that is described as a residue. A residue is a portion of a molecule. In the instant case, the residue has the required elements. It is noted that claim element 'Z' is separate and distinct from formula IIa. As claimed, 'Z' can contain heteroatoms and there is no limitation placed on the length of 'Z'. As claimed, Z can comprise residues that have formula IIa. As such, Z can contain elements other than formula IIa. From the claim language 'Z... comprise at least...' it is clear that Z can encompass more than just formula IIa (see also MPEP section 2111.03). In fact, the claims state that Z can be a hydrocarbon residue which can contain heteroatoms.

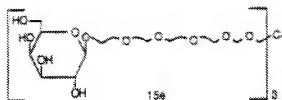
Claims 1-3,13-14,21 are rejected under 35 U.S.C. 102(b) as being anticipated by Biessen et al. (WO 94/04545).

Biessen teach triantennary cluster glycosides, their preparation and use (abstract). On page 12 of the drawings Biessen teach a compound called TG(20A) of structure:

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In comparison to the instant invention the compound of Biessen is of formula Ia of claims 1,21 of the instant invention. Specifically, Z includes the repeating structural element along with a CH₂, that is Z is



Thus Z is a hydrocarbon residue which contains heteroatoms as recited in the instant claims.

Further the compound of Biessen includes N(H)C(O)C(W₂)N(X)C(O), that is



Art Unit: 1654

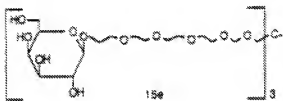
Thus the compound of Biessen includes $N(H)C(O)C(W_2)N(X)C(O)$ as in formula Ia of the instant invention. Each occurrence of W is hydrogen. Each occurrence of X is hydrogen.

V is



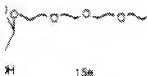
Thus V is a hydrocarbon residue which contains heteroatoms as recited in the instant claims.

Further, the claims recite that the residues V, W, X, and Z together comprise at least two residues (or three residues, see claim 3) which have formula IIa. In the instant case, Z is



It is noted that the number '3' in the structure means that the structural element enclosed in brackets is repeated 3 times (i.e. there are 3 occurrences of the repeated element). Thus, the compound contains 3 occurrences that include $CH-O-(CH_2-CH_2-O)_3-CH_2CH_2$

i.e.



thus meeting the limitations of the instant claims.

It is noted that claim 2 recites that Y (which can be a part of any of V, W, X, and Z) is able to bind a wide range of groups. Although the office has no facility to test the binding capabilities of the compound of Biessen, due to the variety of groups contained in the compound of Biessen there is a reasonable basis that the compound meets the limitations of claim 2, absence evidence to the contrary.

Biessen teach (page 355 1st column last two paragraphs) the use of compound TG(20A) in assays for example (page 21 line 25) so the compound is necessarily part of a composition thus meeting the structural limitations of claims 13-14 of the instant invention. It is noted that the recitation of 'diagnostic' in claim 14 does not result in a structural difference. As such Biessen meet the limitations of claims 1-3, 13-14, 21 of the instant invention.

Response to Arguments 102 rejection Biessen

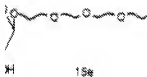
Applicants argue (page 11) that the carbon that is attached to the bracketed element has no hydrogens.

Applicants argue that Biessen has an O-CH₂ portion adjacent the carbon outside the brackets.

Applicant's arguments filed 12/7/09 have been fully considered but they are not persuasive.

Although Applicants argue (page 11) that the carbon that is attached to the bracketed element has no hydrogens, it is noted that as claimed 'Z' can contain heteroatoms and there is no limitation placed on the length of 'Z'. As claimed, Z can comprise residues that have formula IIa. As such, Z can contain elements other than formula IIa. From the claim language 'Z... comprise at least...' it is clear that Z can encompass more than just formula IIa (see also MPEP section 2111.03). In fact, the claims state that Z can be a hydrocarbon residue which can contain heteroatoms.

Although Applicants argue that Biessen has an O-CH₂ portion adjacent the carbon outside the brackets, it is noted that as claimed 'Z' can contain heteroatoms and there is no limitation placed on the length of 'Z'. Importantly, there are 3 occurrences of the residue CH-O-(CH₂-CH₂-O)₃-CH₂CH₂ in the compound of Biessen. In particular the group



appears in the compound of Biessen thus meeting the residue limitations.

Double Patenting

This double patenting rejection is maintained from the previous office action.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3,13-14,21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 11/993,425 (‘425). Although the conflicting claims are not identical, they are not patentably distinct from each other.

‘425 teach compounds (claim 11) of the same general formula of the instant compounds (see instant claims 1,21). ‘425 teach formula IIa (claim 1) as in the instant claims as well as multiple groups of formula IIa (claim 3) (see instant claim 3 for example). ‘425 teach compositions with the compounds (claim 19) (see instant claims 13-14 for example).

It is noted that claim 2 recites that Y (which can be a part of any of V, W, X, and Z) is able to bind a wide range of groups. Although the office has no facility to test the binding capabilities of the compound of '425, due to the variety of groups contained in the compound of '425 there is a reasonable basis that the compound meets the limitations of claim 2, absence evidence to the contrary.

'425 teach the compounds as part of a composition thus meeting the structural limitations of claims 13-14 of the instant invention. It is noted that the recitation of 'diagnostic' in claim 14 does not result in a structural difference.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims are directed to an invention not patentably distinct from claims of commonly assigned 11/993,425 as discussed above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 11/993,425, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Response to Arguments double patenting

Applicants argue (page 12) that they will file a terminal disclaimer once the novelty and non-obviousness of the claimed invention has been acknowledged.

Applicant's arguments filed 12/7/09 have been fully considered but they are not persuasive.

No terminal disclaimer has been filed. The double patenting rejection remains of record.

Conclusion

The 102b rejections and the double patenting rejections are the same rejections that appeared in the previous office action.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/
Primary Examiner, Art Unit 1654

/Ronald T Niebauer/
Examiner, Art Unit 1654

